

TITLE: VA Central IRB Membership Policies**1.0 PURPOSE**

This Standard Operating Procedure (SOP) sets forth the policies and procedures the VA Central IRB uses in recruiting and appointing members to ensure that the composition of the VA Central IRB membership meets all VA and other requirements. It also details member training requirements and member performance evaluation criteria and procedures.

2.0 REVISION HISTORY

Initial Approval Date	August 4, 2008
Revision Dates	December 15, 2008 September 23, 2009 March 17, 2010

3.0 SCOPE

This Standard Operating Procedure applies to all categories of VA Central IRB members. It also applies to staff members of the VA Central IRB Administrative Office, the Program for Research Integrity Development and Education (PRIDE), and the Office of Research and Development (ORD) who are involved in the selection, appointment, training, and evaluation of VA Central IRB members. It also applies to the Institutional Official (IO) for the VHA Central Office (VHACO) Human Research Protection Program (HRPP).

4.0 POLICY

4.1 It is the policy of the VA Central IRB that its membership is composed in accordance with all VA and other federal requirements and that all VA Central IRB members, Co-Chairs, and all VA Central IRB administrative staff involved in management of the VA Central IRB, have the knowledge, skills, and abilities necessary to carry out the functions of the VA Central IRB.

4.2 It is the policy of the VA Central IRB that no member of the Office of Research and Development (ORD) may serve as a voting member of the VA Central IRB. ORD employees may serve in non-voting advisory or consultant roles as needed and/or requested. VA Central IRB administrative staff are not members of the VA Central IRB.

5.0 DEFINITIONS

See VA Central IRB SOP 128, Definitions Used in VA Central IRB SOPs.

6.0 RESPONSIBILITIES

6.1 The Principal Deputy Under Secretary for Health, as the IO for the VHA Central Office (VHACO) HRPP, is responsible for ensuring the appointment of qualified and experienced members to the VA Central IRB. The VHACO IO is responsible for the following:

6.1.1 Directly appoints the VA Central IRB Co-Chairs and suspends or terminates the appointment of any Co-Chair who is not fulfilling the responsibilities and/or obligations of the Chair position.

6.1.2 Approves the appointment of all VA Central IRB voting members.

6.1.3 Annually reviews the performance of the VA Central IRB, including the performance of the Co-Chairs, and takes any action based on the review, to include the termination or suspension of a Co-Chair.

6.2 The Chief Research and Development Officer (CRADO) is responsible for the following:

6.2.1 Appointing VA Central IRB voting and non-voting members, with the exception of the Co-Chairs.

6.2.2 Suspending or terminating the VA Central IRB membership of any individual for whom it is determined that he/she is not fulfilling the member responsibilities and/or obligations.

6.2.3 Annually reviewing the performance of the VA Central IRB, to include the Co-Chairs, and forwarding any recommendations to the VHACO IO.

6.3 The Director, PRIDE, is responsible for the following:

6.3.1 Recruiting qualified members in accordance with VA and other federal guidelines to include:

6.3.1.1 Seeking applications for VA Central IRB members from local VA facilities, VHA Central Office, Veterans, and pertinent fields of expertise in the lay community throughout the country.

6.3.1.2 Evaluating the qualifications of all potential candidates and presenting a list to the CRADO with recommendations for approval of appointment of those individuals who have the required expertise and experience in research; human participant protection regulations; applicable laws; standards of professional conduct and practice; and/or knowledge of or experience with the community from which the participants are drawn.

6.3.2 Annually reviewing the composition and performance of the VA Central IRB and recommending any changes in membership to the CRADO and VHACO IO.

6.3.3 Recruiting and/or approving ad hoc consultants requested by the Co-Chairs to ensure that the necessary expertise is available to the VA Central IRB when the current membership does not have the required ethical, scientific, or other expertise to review specific projects.

6.3.4 Approving or recommending travel or honoraria requests related to the services performed by these individuals.

6.3.5 Participating in the evaluation of the VA Central IRB. See SOP 123, Evaluation of the VA Central IRB.

6.4 The VA Central IRB Administrator is responsible for the following:

6.4.1 Ensuring that upcoming vacancies on the VA Central IRB are promptly identified, recruitment is initiated, and new members appointed or current members re-appointed in order to maintain compositional requirements.

6.4.2 Working with the Director, PRIDE, to arrange for ad hoc consultants as requested by the Co-Chairs.

6.4.3 Ensuring that continuing education is provided to the members either through planned educational activities at convened meetings, attendance at educational conferences, or completion of on-line training as applicable. All continuing education activities are documented in the minutes.

6.5 One of the administrative assistants within PRIDE is assigned responsibility for being the VA Central IRB member point of contact for membership-related issues. This assistant is responsible for the following

6.5.1 Maintaining a folder on each VA Central IRB member that includes the following:

- Copies of VA Central IRB membership appointment letters
- Membership applications
- Local facility endorsement if applicable
- Completed conflict of interest attestations
- Curriculum vitae and resumes
- Training records

6.5.2 Maintaining up-to-date membership rosters on the VA Central IRB shared drive to include contact information, credentials and experience, reviewer category preferences, and training expiration dates.

6.5.3 Ensuring new members are given an orientation and new member orientation and training package.

6.5.4 Ensuring all members complete annual training requirements by tracking training expiration dates and requesting updated certificates of completion as applicable.

6.5.5 Assisting members in coordinating travel requirements in conjunction with the PRIDE travel specialist.

6.5.6 Coordinating reimbursement of member time with their local facilities and with the Office of Research and Development (ORD) Finance Office.

6.6 VA Central IRB members, both voting and non-voting, are responsible for the following:

6.6.1 Submitting to the VA Central IRB Coordinator certificates of completion for all required training in a timely manner

6.6.2 Tracking the time they spend on VA Central IRB activities and providing an accounting to the VA Central IRB Administrative Office at least once per fiscal year.

6.6.3 Complying with all VA Central IRB membership requirements to include:

- Adherence to conflict of interest policies
- Meeting attendance requirements
- Completion of required training in a timely manner
- Performance of reviewer duties as assigned
- Adherence to all VA privacy and information security requirements

6.6.4 Applying the ethical standards of the Belmont Report when reviewing and overseeing research and ensuring all research approved complies with all VA and other requirements.

7.0 PROCEDURES

7.1 Composition of the VA Central IRB. In order to promote thorough ethical and scholarly review of research activities within the purview of the IRB, the VA Central IRB is composed of approximately 10-20 voting members of varying backgrounds from throughout the VA system and from the community at large, and five non-voting members. Ad hoc consultants are used as necessary.

7.1.1 Every non-discriminatory effort will be made to ensure the VA Central IRB voting membership is sufficiently diverse relative to race/ethnicity, gender, cultural background, and sensitivity to community attitudes to promote

respect for the advice and counsel of the VA Central IRB in safeguarding the rights and welfare of human participants. In addition, the VA Central IRB will consist of members who are able to ascertain the acceptability of proposed research in terms of VA research goals and objectives, and the commitment and capability of local VA facilities to perform the research. At a minimum, the VA Central IRB will include one or more voting members from each of the following categories of membership:

7.1.1.1 Scientific members from various disciplines who possess either a medical degree and are board certified in their specialty or a doctoral degree in their area of expertise. At least one of the scientific members must be a licensed physician.

7.1.1.2 Nonscientific members who have expertise in such areas as regulatory affairs, legal affairs, medical ethics, civil rights, patient advocacy, community relations, or other areas that contribute to the complete and thorough review of human participant protections issues for the research projects submitted. At least one and, preferably more, nonscientific members will be appointed.

7.1.1.3 Nonaffiliated members who are not otherwise affiliated with the VA and who are not part of the immediate family of a person who is affiliated with the VA. This category can include Veterans receiving Veteran's benefits who have no other affiliation. All nonaffiliated members are appointed as VA Without Compensation (WOC) employees solely for their service on the VA Central IRB. A nonaffiliated member can also serve in the capacity of a nonscientific member. (See paragraph 5.4 for definition of nonaffiliated.)

7.1.2 The VA Central IRB has five standing nonvoting members appointed by the CRADO to advise the VA Central IRB on matters pertaining to their area of expertise as follows:

- Regulatory Affairs
- Information Security Officer (ISO)
- Legal Advisor
- Privacy Officer
- Ethics Advisor

7.1.3 The VA Central IRB can consult ad hoc advisors as necessary to ensure the appropriate ethical, scientific expertise, or other required expertise, is available to the VA Central IRB.

7.1.4 The CRADO may appoint alternates for any of the voting members, with the exception of the Co-Chairs, or for any of the non-voting members. The appointments must be in writing and will include the name of the specific member or non-voting position for which that appointee can serve as an alternate. Alternate members may attend all VA Central IRB meetings and take

part in all VA Central IRB activities. However, an alternate for a voting member can only vote in the absence of the specific primary member.

7.2 Recruitment of VA Central IRB Members. The Director, PRIDE recruits members from local VA facilities, VHA Central Office, the community of Veterans, and from pertinent fields of expertise or community groups throughout the country.

7.2.1 Potential scientific members will have expertise in their field and be experienced in the conduct of research studies. Also desirable is experience serving on a VA research-related committee or board.

7.2.2 Potential nonscientific members will not have scientific expertise. Prior experience as an IRB member is desirable but not mandatory for nonscientific members. Nonscientific members should have an interest in protecting the health and welfare of Veterans and other human research participants.

7.2.3 Potential nonaffiliated members may be either scientific or nonscientific members. Prior experience as an IRB member is desirable but not mandatory for nonscientific members. Non-affiliated members should have an interest in protecting the health and welfare of Veterans and other human research participants.

7.2.4 The Director, PRIDE, and the VA Central IRB Administrator will make every effort to ensure that the membership of the VA Central IRB has adequate gender, racial, cultural, and geographic representation; as well as expertise in research involving vulnerable participants likely to participate in research overseen by the VA Central IRB, e.g., research with persons with impaired decision-making capability. However, no appointment to the VA Central IRB is made based solely on these criteria.

7.2.5 Individuals identified as potential voting members of the VA Central IRB are required to complete a VA Central IRB Form 100, Application to Become an IRB Member (Attachment 1) and be prepared to commit to the following:

- A three year appointment comprising approximately 1/8th of duty time or five hours per week
- Travel to Washington, DC, for in-person meetings a minimum of twice per year
- Attend a minimum of two-thirds of scheduled monthly meetings either in person or via teleconference or video conference, unless extenuating circumstances permit, i.e., serious illness or military deployment
- Adhere to all VA requirements regarding the privacy and security of VA sensitive information
- Complete a Conflict of Interest Attestation upon appointment

- Complete required training courses

7.2.6 The Co-Chairs of the VA Central IRB are recruited from among current members of the VA Central IRB or current and former Chairs of VA or university affiliate IRBs that serve as IRBs of record for VA facilities. The Co-Chairs are voting members.

7.2.6.1 The Co-Chairs must have extensive experience serving on or chairing an IRB that has reviewed multi-site VA-funded research.

7.2.6.2 The Co-Chair and the Co-Chair's facility must be willing to commit up to 2/8ths of the Co-Chair's duty time in performing VA Central IRB-related functions. VA-ORD reimburses each Co-Chair's facility for up to 25 percent of the Co-Chair's VA salary, or makes comparable arrangements for individuals who are not on the VA payroll. In addition, a Co-Chair must also be prepared to commit to all other requirements as specified in paragraph 7.2.5.

7.2.7 The PRIDE administrative assistant responsible for membership issues performs a List of Excluded Individuals/Entities (LEIE) check on all potential members and documents the results of the check. If a potential member's name appears on the list, they may not be further considered for membership.

7.2.8 The Director, PRIDE, forwards all qualified applicants' names and application materials to the CRADO with recommendations for final selection and appointment. Recommendations for the position of Co-Chair will be forwarded through the CRADO to the VHACO IO for consideration.

7.3 Appointment of Members. Member appointment requirements and the appointment process are as follows:

7.3.1 Individuals selected for voting membership on the VA Central IRB, to include the Co-Chairs, are required to complete and submit additional documentation as follows:

7.3.1.1 All voting members who are VA employees (with the exception of WOC employees) must submit an endorsement from their facility indicating that the employee will be given the amount of duty time needed to fulfill the obligations of a VA Central IRB member. This endorsement is documented on VA Central IRB Form 101, Endorsement for Appointment (Attachment 2). VA-ORD reimburses the member's facility for up to 1/8th of the member's VA salary per year and up to 2/8ths for the Co-Chairs. The VA member and the member's supervisor sign the form.

7.3.1.2 The Director, PRIDE, signs an acknowledgement of receipt on the VA Central IRB Form 101 and a copy is kept on file in the

member's record. This form is re-submitted upon expiration of a member's current appointment and subsequent re-appointment for an additional term.

7.3.2 All members, including nonvoting members, are required to complete VA Central IRB Form 102, Conflict of Interest Attestation (IRB Members) (Attachment 3) and read the "VA Standards of Conduct and What May Constitute a Real or Potential Conflict of Interest" (Attachment 4). This form is again completed and re-submitted upon official re-appointment of a VA Central IRB Board member for an additional term.

7.3.3 Nonaffiliated members are required to complete additional paperwork for their appointments as VA WOC employees. This includes the signing of a formal WOC agreement. The VA Central IRB Administrator assists all nonaffiliated members with the WOC appointment process.

7.3.4 All members must have a background check completed that meets VHA Central Office Human Resources recommendations that is current within one year of their appointment date. If a member does not have these or they are out-of-date, PRIDE administrative staff will assist the members in completing the paperwork and in arranging for the fingerprinting and checks to be performed as soon as they are appointed.

7.3.5 All members are appointed for a period of three years, with the exception of the Co-Chairs, who are appointed/re-appointed on a yearly basis. Members and Co-Chairs may be re-appointed to unlimited additional terms.

7.3.6 The original, signed appointment letter is sent to all members upon signature of the signatory authority and copies are maintained by the responsible PRIDE administrative assistant.

7.3.6.1 For the voting members the signatory authority is the CRADO, with the exception of the Co-Chairs. Upon signature of the CRADO, the appointment is then forwarded to the IO for review and concurrence. The signatory authority for appointment of the Co-Chairs is the VHA Central Office IO. Upon signature on the appointment letter, a member can participate in all activities of the VA Central IRB to include voting. If background checks are still pending, the appointment letter will indicate the appointment will be terminated if the results of the background check are not satisfactory.

7.3.6.2 For the non-voting members, the signatory authority is the CRADO. Prior to approving the appointment, the appointee's supervisor is contacted to verify that the individual can serve on the VA Central IRB as part of the individual's official duties. Concurrence from the supervisor will be required in writing. No reimbursement is provided to the nonvoting member's facility or office for the time spent by non-voting members on VA Central IRB duties, however, travel expenses can be reimbursed if requested.

7.3.6.3 Once the results of the background check(s) is received, this information is forwarded to the IO through the CRADO for information or action as appropriate.

7.3.7 Upon receipt of the appointment letter, all new members, regardless of member category or voting status, are scheduled by the VA Central IRB Administrator for a VA Central IRB member orientation. This orientation includes a review of the following:

- Pertinent VA and other federal regulations and policies
- VA Central IRB Standard Operating Procedures (SOPs)
- Belmont Report and other ethical guidelines
- Use of teleconferencing and video conferencing capabilities
- Requirements for appropriate management of any VA-owned equipment that may be issued
- VA Central IRB website
- Training requirements
- Travel policy requirements

7.3.8 All members, regardless of voting status or member category, must also submit evidence of current completion of the following required training courses to the VA Central IRB administrative staff within 90 days of their appointment to the VA Central IRB. For all recurring training requirements, updated evidence of training completion must be submitted to demonstrate the member is up-to-date. The PRIDE administrative assistant tracks the completion of all initial and recurring training requirements in accordance with VA Central IRB SOP 201, VA Central IRB Member Administration.

- VA Privacy Awareness or VHA Privacy Policy web training (yearly)
- VA Information Security Awareness (yearly)
- VA Information Security 201 (a one-time requirement)
- Good Clinical Practices and Human Subjects Protection ORD-approved course (CITI). Other approved training may be substituted for this requirement upon the approval of the Director, PRIDE.
- The three assurance modules on the OHRP website (Co-Chairs only)
- Other required training as determined by the VA and other federal agencies

WOC employees may have additional training requirements depending upon the specific VA personnel office to which they will be assigned.

7.3.9 Within their first 90 days of membership, voting members also complete a VA Central IRB Form 128, Reviewer Survey (Attachment 5), indicating the types of projects they feel comfortable serving in the role of a primary or secondary reviewer of projects undergoing review by the convened IRB or as the primary reviewer for projects undergoing expedited review.

7.3.10 VA Central IRB members are encouraged to attend the annual Public Responsibility in Medicine (PRIM&R) Conference, as well as other conferences as deemed appropriate by the Director, PRIDE. Attendance at such conferences by VA Central IRB members will be funded through the VA Central IRB budget. The VA Central IRB Administrative Office will coordinate and track member attendance at these conferences per VA Central IRB SOP 201.

7.4 Evaluation of VA Central IRB Member Performance. The Director, PRIDE, annually reviews the performance of the VA Central IRB membership and re-evaluates its composition, recommending adjustments as needed to the CRADO and VHACO IO in order to ensure that the IRB continues to meet VA and other requirements.

7.4.1 The individual performance of VA Central IRB voting members is evaluated based on the factors listed below.

- Number of meetings attended and active participation in discussion
- Completion of all required training
- Adherence to COI requirements
- Willingness to serve as a primary reviewer or secondary reviewer and number of projects presented as primary or secondary reviewer (Scientific members)
- Willingness to serve as an Informed Consent Reviewer and number of projects presented as an Informed Consent Reviewer (both scientific and nonscientific members)
- Participation in expedited reviews or exemption determinations if designated by the Co-Chair
- Adherence to all VA and other applicable requirements in regard to the protection of human participants, including security and privacy of sensitive research information

7.4.2 The performance of the VA Central IRB Co-Chairs is also reviewed annually by the Director, PRIDE, the CRADO, and the VHACO IO. The Co-Chairs are evaluated based on the following factors:

- Number of meetings attended and chaired during the year, both in person and via teleconference or video conference
- Completion of required training, to include any recurring training
- Adherence to conflict of interest requirements
- Demonstrated ability to effectively facilitate convened meetings so that reviews are timely, thorough, and appropriately fulfill the IRB's responsibilities
- Adequate identification of the need for Ad hoc Consultants
- Timeliness in completing expedited reviews and reviewing exemption requests and/or in designating other members to complete these functions
- Ability to take necessary actions in response to unanticipated problems and/or serious adverse events

- Timeliness in reviewing and signing meeting minutes and other project-related documents such as project review actions and continuing review approvals (electronically or manually)
- Adherence to all VA and other requirements in regard to the protection of human participants, as well as security and privacy of sensitive research information

7.4.3 The individual performance of VA Central IRB non-voting members is evaluated based on the factors listed below.

- Number of meetings attended
- Completion of all training, to include recurring training
- Adherence to COI requirements
- Performance of reviews required by their expertise
- Provision of expert opinion as requested by Co-Chairs during meeting
- Adherence to all VA requirements and other in regard to the protection of human participants, including security and privacy of sensitive research information

7.4.4 Group feedback on the performance of the VA Central IRB and VA Central IRB member is provided at convened meetings of the VA Central IRB by the VA Central IRB Administrator on a no less than yearly basis. If a particular member is determined to not be meeting his/her obligations, the Director, PRIDE, will provide feedback to the member individually. If there is no improvement, the Director, PRIDE, will recommend to the CRADO, or the IO, if the member is a Co-Chair, that the member's appointment be terminated or allowed to expire, depending upon the length of time remaining on the appointment.

7.5 Resignation of VA Central IRB Members. VA Central IRB members will notify both the VA Central IRB Co-Chairs and the VA Central IRB Administrator if they intend to resign from the VA Central IRB.

7.5.1 Members who resign prior to the expiration of their current term are asked to give at least a 60-day notice in writing via e-mail or a memorandum or letter to allow sufficient time for an appropriate replacement to be named.

7.5.2 Members whose terms are expiring and who do not wish to seek re-appointment are also asked to give at least a 60-day notice in writing of their intention to no longer serve after the end of their current term.

8.0 REFERENCES

8.1 38 CFR 16, Department of Veterans Affairs, Protection of Human Subjects

8.2 VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research

8.3 VHA Handbook 1058.03, Assurance for Protection of Human Subjects in Research

5 Attachments

1. VA Central IRB Form 100, Application to Become an IRB Member
2. VA Central IRB Form 101, Endorsement for Appointment
3. VA Central IRB Form 102, IRB Member Conflict of Interest Attestation
4. VA Standards of Ethical Conduct and What May Constitute a Real or Potential Conflict of Interest (For VA Central IRB members)
5. VA Central IRB Form 128, Reviewer Survey

I have reviewed and approved the content of this SOP.


K. Lynn Cates, MD
Director, PRIDE

Date: 4/2/2010

Application to Become an IRB Member



Instructions:

The Department of Veterans Affairs, Office of Research and Development (ORD), is seeking individuals with IRB experience from across the country, to include current VA employees and non-VA-affiliated personnel, to apply to become a member of the VA Central Institutional Review Board (IRB). The purpose of the VA Central IRB is to ensure appropriate ethical and scientific review of selected ORD multi-site projects and to enhance the efficiency and timeliness of required reviews.

VA-affiliated applicants must ensure that they will be allowed time by their facilities to participate. Local VA facilities will be reimbursed for this time by ORD up to 1/8th of the VA-affiliated member's salary or up to 2/8ths for Co-Chairs. Travel expenses for both VA and non-VA-affiliated members will be covered by ORD.

Applicants will be required to meet the following criteria **if selected** to become a member of the VA Central IRB:

- A three year commitment comprising approximately 1/8th of duty time or approximately 5 hours a week on average for members
- Travel to Washington, DC a minimum of twice per year.
- Attendance at two-thirds of monthly VA Central IRB meetings (in person or via audio/video conference).
- Completion of all required training courses.
- Completion of a Conflict of Interest Attestation.
- For VA employees, submission of an Endorsement of Membership form from their local facility.
- For non-affiliated members, completion of any additional paperwork required for a VA Without Compensation (WOC) appointment.
- Completion of a successful background check current within one year of appointment

Our goal is to develop the VA Central IRB as a national model that will enhance human research participant protections. If you would like to join us in this effort, please complete the attached application form, attach a CV (or resume for non-scientists) and express mail (**not regular postal service mail**) the completed application to the following address:

K. Lynn Cates, MD
Office of Research and Development/PRIDE
Department of Veterans Affairs
810 Vermont Avenue, NW (12)
Washington, DC 20420
FAX: 202-254-0162

Alternatively, the application package can be faxed to the fax number listed above or e-mailed with digital signature to one of the PRIDE staff members listed below.

Any further questions concerning membership requirements or the goals and objectives of the VA Central IRB can be directed to Lynn Cates, Director of PRIDE, at lynn.cates@va.gov or Annette Anderson, VA Central IRB Administrator, at annette.anderson3@va.gov or 202-461-1813.

APPLICATION TO BECOME A VA CENTRAL IRB MEMBER

I. DEMOGRAPHIC INFORMATION:

Name: _____
(First, Middle Initial, Last Name)

Credentials/Degrees:

Job Title:

Work Address: (Home Address if Applicable)

(Address Line 1)

Telephone:

Fax:

(City, State, Zip)

Cell Phone:

The following are requested but optional:

Age:

Sex:

Race:

Ethnicity:

Do you have a VA-owned laptop issued for your use? ☐ Yes ☐ No

Do you have VPN? ☐ Yes ☐ No Do you have PKI? ☐ Yes ☐ No

II. EXPERIENCE: Please check all that apply in regard to your experience/status

Veteran <input type="checkbox"/>	Physician <input type="checkbox"/>	Information Security Officer <input type="checkbox"/>
VA Employee <input type="checkbox"/>	Nurse <input type="checkbox"/>	Chief Information Officer <input type="checkbox"/>
Prior IRB Member <input type="checkbox"/>	Pharmacist <input type="checkbox"/>	Privacy/HIPAA <input type="checkbox"/>
Prior IRB Chair <input type="checkbox"/>	Public Health/ Epidemiology <input type="checkbox"/>	Health Services Research (HSR&D) <input type="checkbox"/>
FDA Experience <input type="checkbox"/>	Genomics <input type="checkbox"/>	Rehabilitation Research <input type="checkbox"/>
Quality/Compliance <input type="checkbox"/>	Biostatistician <input type="checkbox"/>	Social/ Behavioral Research <input type="checkbox"/>
Survey Design <input type="checkbox"/>	Ethicist <input type="checkbox"/>	VA Cooperative Studies Program (CSP) <input type="checkbox"/>
Non-Profit <input type="checkbox"/>	Economist <input type="checkbox"/>	VA CSP Human Rights Committee <input type="checkbox"/>
Non-Scientist <input type="checkbox"/>	Lawyer <input type="checkbox"/>	Non-Affiliated to VA <input type="checkbox"/> (Note: You are considered affiliated if an immediate family member is affiliated)
Scientist: (Researcher) <input type="checkbox"/>	For physicians, nurses, and other scientists, please indicate your specialty:	

III. HUMAN SUBJECTS PROTECTION EXPERIENCE: *Provide a brief response (less than two pages) to the following: (Text box will expand as needed.)*

1. Please describe your familiarity with human research, human research protections, and any related experience or qualifications:
2. Please describe any experiences with vulnerable populations (e.g., decisionally impaired subjects):
3. Please explain why you would like to serve on the VA Central IRB:

Please attach a current CV or resume. (Please ensure your SSN is not included on your CV or resume)

Please sign and date this application and provide your e-mail address.

Signature

Date Submitted: _____

Preferred E-mail Address: _____
(For VA employees this must be your VA e-mail address)

The Office of Research and Development, Department of Veterans Affairs, is collecting this information to evaluate an applicant's qualifications to serve on the VA Central IRB. It will be used to ensure that the VA Central IRB meets all VA and other federal requirements pertaining to IRB membership composition. It is estimated that the form will take approximately 20 minutes to complete. Responses are entirely voluntary. All information collected will remain confidential. The forms will be kept on file for a period of one year or for the duration of a member's appointment on the VA Central IRB.

Endorsement for Appointment



Section 1: Potential Member

I am being considered for appointment as a member of the VA Central IRB. I certify that I will carry out the duties of a VA Central IRB member to the best of my abilities and that I will devote the necessary time (approximately 5 hours per week if member, 10 hours if Chair) to ensure that the rights and welfare of participants in human research are protected.

Applicant's Signature

Date

Member's Full Name (Printed)

Section 2: Potential Member's Supervisor

I endorse the above-named applicant's membership on the VA Central IRB and I certify that the applicant will be afforded the necessary duty time to carry out his/her duties as a VA Central IRB member, to include a minimum of two or more trips to Washington, DC, each year as required. I understand that the applicant's VA medical facility will be reimbursed for the duty time spent by the applicant on VA Central IRB duties up to 1/8 (2/8 if applicant is Chair) of the applicant's VA salary, to include benefits.

Applicant's Supervisor's Signature

Date

Supervisor's Full Name (Printed)

Supervisor's Title

Medical Center Director's Signature

Date

Section 3: Director, PRIDE

I acknowledge receipt of this applicant's endorsement as a member of the VA Central IRB. Arrangements will be made to transfer funding to the applicant's VA facility to cover the applicant's salary expenses for the time spent on VA Central IRB duties. Travel expenses will be reimbursed on a per trip basis to the member's VA facility upon request and submission of a completed expense report.

K. Lynn Cates, MD
Director, PRIDE

Date

IRB Member Conflict of Interest Attestation



THIS COMPLETED FORM WILL ONLY BE REVIEWED BY PERSONNEL ON AN "AS NEEDED" BASIS WHEN REQUIRED BY THE RESPONSIBILITIES OF THEIR POSITION.

ALL INFORMATION CONTAINED IN THIS FORM WILL REMAIN CONFIDENTIAL AND HAVE ONLY LIMITED DISTRIBUTION.

This form must be completed, signed, and submitted by each VA Central IRB member at the time of initial appointment and at the time of re-appointment. It is used to document that each VA Central IRB member understands what is a perceived or a real conflict of interest and that they are aware of their responsibility to recuse themselves from the review of any projects submitted to the VA Central IRB in which they have a real or potential conflict of interest.

Please answer the following questions in each section as applicable. Provide additional documentation as necessary per requested below.

Background:

1. Name:
2. Date of Appointment/Reappointment to the VA Central IRB:
3. Role (check all that apply):
☐ Scientific Member ☐ Non-Scientific Member
☐ Non-Affiliated Member ☐ Community Member
☐ Ad Hoc Member ☐ Non-Voting Member
4. You are a: ☐ VA Employee ☐ Without Compensation Employee
5. VA Institution Assigned:
6. Are you an active investigator? ☐ Yes ☐ No

If yes, please list all your active research projects and the starting and **projected** end dates:

Name of Project	Start Date	End Date

Add more lines as needed (Word Table)

Conflict of Interest Attestation

VA Central IRB members must check all the below boxes:

- ☐ I have read the attached "VA Standards of Ethical Conduct and What May Constitute a Real or Potential Conflict of Interest."
- ☐ I will not participate in the initial or continuing review of any project; the review of any project modifications; or the review of adverse or unanticipated events, complaints, or noncompliance with regulations or VA IRB policies and procedures, in which I, an immediate family member, or any other person with whom I have an imputed interest or in which I have a potential personal or financial conflict of interest, except to provide information requested by one of the VA Central IRB Co-Chairs.
- ☐ If I do have a potential conflict with any research project before the VA Central IRB for review, I will immediately recuse myself from the review and leave the room for the duration of the Board's discussion of that project, unless requested by one of the Co-Chairs to remain to provide information. Upon providing the information, I will immediately leave the room until after a vote on the project in question has been recorded. If assigned a project as a reviewer, I will immediately declare the conflict and return the project to the VA Central IRB Administrative Office.
- ☐ I understand that not recusing myself from the review of any research projects that could involve real or potential conflicts of interests or the providing of false information, may be punishable by fine or imprisonment (U.S. Code, Title 18, section 1001).

Signature

Date

Printed Name

For VA Central IRB Members

VA Standards of Ethical Conduct and What May Constitute a Real or Potential Conflict of Interest

Basic Obligations of Public Service

Public service is a public trust. To ensure that every citizen and human subject can have complete confidence in the integrity of the Department of Veterans Affairs research protocol submission, approval, and monitoring processes, as well as in the conduct of the research, each VA investigator and each VA Central IRB member must respect and adhere to the principle of ethical conduct as set forth in 5 CFR 2635, Standards of Ethical Conduct for Employees of the Executive Branch, and must disclose and manage any conflicts of interest.

The following principles apply to every investigator and VA Central IRB Board Member:

- Public service is a public trust, requiring employees to place loyalty to the Constitution, the laws, and ethical principles above private gain.
- Employees shall not hold financial interests that conflict with the conscientious performance of duty.
- Employees shall not engage in financial transactions using nonpublic government information or allow the improper use of such information to further any private interest
- Employees shall not solicit or accept any gift or other item of monetary value from any person or entity seeking official action from, doing business with, or conducting activities regulated by the employee's agency, or whose interests may be substantially affected by the performance or nonperformance of the employee's duties.
- Employees shall not use public office for private gain.
- Employees shall act impartially and not give preferential treatment to any private organization or individual.
- Employees shall protect and conserve public property and shall not use it for other than authorized activities.
- Employees shall not engage in outside employment activities, including seeking or negotiating for employment, that conflict with official government duties and responsibilities.

While all government employees must adhere to all the above principles, there are several of these principles which investigators involved in human subjects research and VA Central IRB Board members can expect to receive greater scrutiny. These involve real or potential conflicts of interest, particularly financial, and the acceptance of gifts.

Financial Conflicts of Interest (FCOI)

In accordance with 5 CFR 2635, government employees are prohibited from participating personally and substantially in an official capacity in any particular matter in which, to his/her knowledge, he/she, or any person whose interests are imputed to him/her, has a financial interest, if the particular matter will have a direct and predicable effect on that interest. A particular matter will have a direct effect on a financial interest if there is a close causal link between any decision or action to be taken in the matter and any expected effect of the matter on the financial interest. An effect may be direct even though it does not occur immediately.

The financial interests of the following persons are considered to be **imputed** interests to the investigator and will serve to disqualify an investigator to the same extent as if they were the investigator's own interests:

- Employee's spouse
- Employee's minor child
- Employee's general partner in a business
- An organization in which the employee serves as officer, director, trustee, general partner, or employee
- Any person with whom the employee is negotiating or has an arrangement concerning prospective employment

The following are considered significant financial conflicts of interest including but not limited to the following monetary interests, as qualified by the following paragraphs:

- Non-VA salary or other payments for services from private or for-profit entities (e.g., consulting fees or honoraria)
- Compensation to the investigator if the amount of the compensation could be affected by study outcome
- Equity interests (e.g., stocks stock options, or other ownership interests)
- Intellectual property rights (e.g., patents, copyrights, and royalties from such rights) that would reasonably be expected or appear to affect the proposed research
- Consulting fees, honoraria, gifts, or other "in kind" compensation from a financially interested company for any purpose not directly related to the reasonable costs of the research that in the aggregate have in the prior calendar year exceeded \$10,000, or are expected to exceed that amount in the next 12 months
- Any non-royalty payments or entitlements to payments in connection with the proposed research that are not directly related to the reasonable costs of the research, including any bonuses or milestone payments to the investigators in excess of reasonable costs incurred
- Service as an officer, director, or in any other fiduciary role for a company with financial interests in the proposed research

NOTE: A FCOI can only be ruled out by consultation with a Deputy Ethics Officer within the VA Office of General Counsel, or within the Office of General Counsel at the VA Central Office.

Significant financial conflicts of interest do not include:

- Salary, royalties or other remuneration from the applicant's home institution
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities
- Income from service on advisory committees or review panels for public or non-profit entities

Where a VA Central IRB Board member knows that a particular matter involving a protocol to be reviewed by the VA Central IRB is likely to have a direct and predictable effect on the financial interests of any of his/her imputed interests or where the VA Central IRB member determines that the circumstances would cause a reasonable person with knowledge of the relevant facts to question his/her impartiality in the matter, the VA Central IRB Board member must immediately recuse himself/herself from the review of that particular protocol or matter. This includes leaving a fully convened meeting during the deliberation and vote on the protocol or particular matter and only returning after the discussion is complete. The only exception is when the Board Chair asks the member to remain to answer any questions. Once all questions have been answered, the member must leave the meeting. If a member is assigned a protocol for review, he/she must immediately return it to the VA Central IRB Administrative Office if a real or the appearance of conflict of interest exists.

Acceptance of Gifts

With a few exceptions, an investigator or a VA Central IRB Board member, shall not, directly or indirectly, solicit or accept a gift from a **prohibited source** or which is given because of the employee's official position or function.

A **prohibited source** is any person who meets one or more of the following criteria:

- Is seeking official action by the employee's agency
- Does business or seeks to do business with the employee's agency
- Conducts activities regulated by the employee's agency
- Has interests that may be substantially affected by performance or nonperformance of the employee's official duties
- Is an organization, the majority of whose members are engaged in or have interests in the activities described in the above bullets

In general, a government employee may not:

- Accept a gift in return for being influenced in the performance of an official act or for reviewing a particular protocol
- Solicit or coerce the offering of a gift
- Accept gifts from the same or different sources on a basis so frequent that a reasonable person would be led to believe the employee had a conflict of interest
- Receive any salary or any contribution to or supplementation of salary from any source other than the United States as compensation for services as a government employee
- Accept vendor promotional training contrary to applicable regulations, policies, or guidance relating to the procurement of supplies and services for the government.

A gift is any gratuity, favor, discount, entertainment, hospitality, loan, forbearance, or other item having monetary value. It includes services as well as gifts of training, transportation, local travel, lodgings and meals, whether provided in-kind, by purchase of a ticket, payment in advance, or reimbursement after the expense has been incurred. It **does not** include the following:

- Modest items of food and refreshments, such as soft drinks, coffee, and donuts, offered other than as part of a meal
- Greeting cards and items with little intrinsic value, such as plaques, certificates, and trophies, which are intended solely for presentation
- Loans from banks and other financial institutions on terms generally available to the public
- Opportunities and benefits, including favorable rates and commercial discounts, available to the public or to a class consisting of all federal government employees, whether or not restricted on the basis of geographic considerations
- Rewards and prizes given to competitors in contests or events, including random drawings, open to the public unless the employee's entry into the contest or event is required as part of their official duties
- Pension and other benefits resulting from continued participation in an employee welfare and benefits plan maintained by a former employer
- Anything which is paid for by the government or secured by the government under government contract
- Anything for which market value is paid for by the employee

There are many exceptions to the prohibition on accepting gifts. Only a few of the more common ones are detailed below. **When in doubt about the acceptance of a gift, you should contact your Regional Counsel.**

- A government employee may accept unsolicited gifts having an aggregate market value of **\$20.00 or less per source per occasion** provided that the aggregate market value of the individual gifts received from any one person shall not exceed **\$50 in a calendar year**. This exception does not apply to gifts of cash or of investment interests such as stock, bonds, or certificates of deposit, which are strictly prohibited.
- A government employee may accept a gift given under circumstances which make it clear that the gift is motivated by a family or personal friendship rather than the position of the employee. Relevant factors in making such a determination include the history of the relationship and whether the family member or friend personally pays for the gift.
- A government employee may accept discounts and other similar opportunities and benefits if they are offered to all government employees or to members of a group, class, or organization to which the investigator belongs that is not related to their government employment or does not otherwise discriminate among government employees on the basis of their official position or rank.

Other Potential Conflicts of Interest

Two other areas that may result in a conflict of interest or the appearance of a conflict of interest that require a short mention are the **use of nonpublic information and compensation for teaching, speaking and writing**.

A government employee shall not engage in a financial transaction using nonpublic information, nor allow the improper use of nonpublic information to further his/her own

private interest or that of another, whether through advice or recommendation, or by knowing unauthorized disclosure. Nonpublic information is information that the employee gains by reason of federal employment and that he/she knows or reasonably should know has not been made available to the general public.

Finally, a government employee should not receive compensation from any source for teaching, speaking, and writing other than the government, that relates to his/her official duties. This generally means an employee may not be compensated for teaching, speaking, or writing on any matter to which the employee is presently assigned or to which the employee had been assigned during the previous one-year period or on any ongoing or announced policy, program, or operation of the employee's agency. There are many nuances to this particular prohibition, such as teaching certain courses in a regularly established curriculum of an institution of higher education. Again, if in doubt, please consult your Regional Counsel.

Disclosure of Conflicts of Interest

Where a VA Central IRB member knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interests of any of his/her imputed interests or where the VA Central IRB member determines that the circumstances would cause a reasonable person with knowledge of the relevant facts to question his/her impartiality in the matter, the VA Central IRB member must **disclose** to the VA Central IRB that a conflict of interest exists and not participate in the review of the particular matter.

After reading this information, each VA Central IRB Board member must complete a VA Central IRB Form 102, IRB Member Conflict of Interest Attestation submit it to the VA Central IRB Administrative Office via fax, express mail, or encrypted or pass-word protected digitally signed e-mail..

Reviewer Survey



VA Central IRB Member Name: _____

Please indicate by checking the applicable boxes below, what types of research projects you are comfortable serving as a Primary or Secondary Reviewer, or in the capacity of a designated Expedited Reviewer. Your responses will be used by the VA Central IRB administrative staff and the Co-Chairs to assist them in assigning reviewers. Thank you for your cooperation.

- | | |
|---|--|
| <input type="checkbox"/> Survey Research | <input type="checkbox"/> Public Health/Epidemiology |
| <input type="checkbox"/> Tissue Banks | <input type="checkbox"/> Genomics/ Pharmacogenomics |
| <input type="checkbox"/> Data Banks Research | <input type="checkbox"/> Observational Studies |
| <input type="checkbox"/> Health Services Research | <input type="checkbox"/> Quality of Care/Outcomes |
| <input type="checkbox"/> Health Economics | <input type="checkbox"/> Health Disparities |
| <input type="checkbox"/> Clinical Trials/CSP Studies | <input type="checkbox"/> Clinical Translational Research |
| <input type="checkbox"/> Preventive Medicine/Research | <input type="checkbox"/> Nursing |
| <input type="checkbox"/> Investigational Drugs | <input type="checkbox"/> Pharmacokinetics |
| <input type="checkbox"/> Investigational Devices | <input type="checkbox"/> Social/ Behavioral Research |

Fields of Clinical Expertise: *(Please check all that apply)*

- | | | |
|--|---|--|
| <input type="checkbox"/> Allergy | <input type="checkbox"/> Cardiology | <input type="checkbox"/> Dermatology |
| <input type="checkbox"/> Endocrinology | <input type="checkbox"/> Gerontology | <input type="checkbox"/> ID/Microbiology |
| <input type="checkbox"/> Internal Medicine | <input type="checkbox"/> Neurology | <input type="checkbox"/> Oncology |
| <input type="checkbox"/> Mental Health | <input type="checkbox"/> Radiology/Imaging | <input type="checkbox"/> Pathology |
| <input type="checkbox"/> Gastroenterology | <input type="checkbox"/> Toxicology | <input type="checkbox"/> Critical Care |
| <input type="checkbox"/> Chemistry | <input type="checkbox"/> Hematology | <input type="checkbox"/> Orthopedics |
| <input type="checkbox"/> Pulmonary | <input type="checkbox"/> Emergency Medicine | <input type="checkbox"/> Otolaryngology |
| <input type="checkbox"/> Urology | <input type="checkbox"/> Gynecology | <input type="checkbox"/> Nephrology |
| <input type="checkbox"/> Dental/Oral | <input type="checkbox"/> Rehabilitation | |
| <input type="checkbox"/> Other/Subspecialties: _____ | | |